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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,682	04/28/2000	DAVID J. FITZGERALD	015280-31010	5396

7590

09/16/2002

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[REDACTED] EXAMINER

PORTNER, VIRGINIA ALLEN

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1645

DATE MAILED: 09/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/462,682</b>	Applicant(s) <b>Fitzgerald</b>
	Examiner <b>Portner</b>	Art Unit <b>1645</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on May 28, 2002
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-9, 11-26, 28, 31, 32, 34-36, and 39-45 is/are pending in the application.
- 4a) Of the above, claim(s) 4-6, 11, 14-23, 26, 28, 31, 32, 34-36, and 39-43 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-3, 7-9, 12, 13, 24, 25, 44, and 45 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1-9, 11-26, 28, 31, 32, 34-36, and 39-45 are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 14
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

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**DETAILED ACTION**

Claims 10, 27, 29, 30, 33, 37-38 have been canceled.

Claims 1-2, 7, 12, 24-25 have been amended.

New claims 44-45 have been submitted.

Claims 4-6, 11, 14-15, 16-18 (claims 16-18 recite specific species of invention not elected), 19-23, 26 (species not elected), 28, 31, 32, 34-36, 39 and 40-43 are withdrawn from further consideration as drawn to non-elected inventions.

Claims 1-3, 7-9, 12-13, 24-25, and 44-45 are under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Information Disclosure Statement***

2. The information disclosure statement filed May 28, 2002 has been considered.

***Rejections Withdrawn***

3. Claims 27, 29-30, 33, 37-38 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation and administration of an immunogenic chimeric PE-like molecule that comprises a non-native epitope, does not reasonably provide enablement for the use of the immunogen for stimulation of a protective immune response for the prophylactic or therapeutic treatment of any disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the invention commensurate in scope with these claims, in light of the cancellation of claims.

4. Claims 10, 27, 30, 33 and 37-38 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of the claims having been canceled.

5. Claims 12, 24-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of claim 12 having been clarified, claim 24 having an additional methods step added and claim 25 having been amended to recite claim limitations that could define an epitope.

6. Claims 1, 2, 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of the clarifying statements and amendments of the claims (ie., claim 7 now recites SEQ ID No 2).

7. Claims 9 (partially obviated), are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, wherein the claim has been amended to more clearly define where the non-native epitope is located.

8. Claims 1-3, 7-10, 12-13, 24-25, 27, 29, 30, 33, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cryz et al (1995) in view Moore (1992) and Pastan et

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al (US Pat. 5,328,984), in light of the PND epitope not comprising two cysteine amino acids to preserve the cysteine loop of the native epitope.

9. Claims 1-3, 7-9, 12-13, under 35 U.S.C. 102(b) as being anticipated by Pastan et al (US Pat. 5,328,984), in light of the amendment of the claims to recite two cysteines of PE.

10. Claims 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Pastan et al (US Pat. 5,328,984), in light of the amendment of the claims to recite two cysteines of PE.

11. Claims 24-25, and 44-45 rejected under 35 U.S.C. 103(a) as being unpatentable over Pastan et al (US Pat. 5,328,984) as applied to claims 1-3, 7-10, 12-13, 27, 29-30, 33 immediately above, in view of Pastan (US Pat. 6,074,644), in light of the amendment of the claims to recite two cysteines of PE.

***Rejections Maintained/ Response to Arguments***

12. The rejection of claim 8 under 35 U.S.C. 112, second paragraph is asserted to be clear in light of the definition provided in the specification.

13. It is the position of the examiner that claim 8 rejected under 35 U.S.C. 112, second paragraph, is still indefinite because claim 1 has not been amended to require any specific percentage identity, nor to recite the phrase “at least” as argued. The translocation domain is not limited to a PE domain that differs in sequence, but is directed to a sequence from any source that shares sequence identity. This rejection could be obviated by amending the claim 1 to recite --is, or is substantially identical to, domain II of PE--, or an equivalent phrase that provides for the sequence to be the sequence of domain II of PE.

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14. The rejection of claim 9 under 35 U.S.C. 112, second paragraph is asserted to be clear in light of the amendment of claim 1 to clarify the components referred to by claim 9.
15. It is the position of the examiner that claim 9 (partially maintained), rejected under 35 U.S.C. 112, second paragraph, is still indefinite because with the amendment of claim 1 defining the two cysteines to be from PE and dependent claim 9 not requiring the cysteines be PE cysteines; claim 9 still broadens the scope of claim 1 from which it depends because the cysteines of claim 1 are from PE and the cysteines of claim 9 are from any source.

***New Claims/New Claim Limitations/New Grounds of Rejection***

***Claim Rejections - 35 U.S.C. § 112***

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 1-3,7-9, 12-13, 24-25 and 44-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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At page 27, subparagraph D, a single species of invention is described. Original descriptive support is provided for a chimeric immunogen that comprises PE domains Ib, II and III, with a non-native epitope inserted in domain Ib of PE.

A single species does not provide teaching or disclosure for the recitation of a genus of immunogenic chimeric non-toxin molecules that comprise any ER domain from any source and of any size, together with any sequence of amino acids that shares similarity to domain II of any size or sequence, together with any sequence that comprises two cysteines that form a loop with a non-native epitope within the loop when the instant specification only describes a single species of chimeric non-toxin molecule that comprises Ib, II and III of PE. The newly submitted claim limitations define a genus of invention defined by a phrase that does not flow from the specification and is therefore considered to encompass new matter. See *In re ANDERSON*, 176 USPQ 331 (CCPA 1973).

As the instant specification does not disclose and provide original descriptive support for the genus of claimed chimeric immunogens which comprise any epitope presenting domain located in between the translocation domain and the ER retention domain. The specification does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the full scope of the claimed invention. The newly introduced claim limitations constitute NEW Matter.

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19. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 1-3, 7-9, 11-12, 24-25 and 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All of the claims recite the phrase “two cysteine residues native to PE”. As the cysteine residues are not so claimed to be in relationship to any other amino acid sequence of PE, how are the two cysteine residues native to PE distinguished from any other cysteine residues that are non-native to PE? A cysteine is a cysteine whether it is found in PE or in any other amino acid sequence and absence the cysteine being apart of an amino acid sequence that is PE specific, how would one cysteine be distinguished from another? The broad recitation of any two cysteines of PE absent any specific context is confusing. Are there any other PE amino acids in association with the two cysteine residues native to PE that are apart of the “non-native epitope domain”? How would one distinguish non-native cysteines from native cysteines as all cysteines have the same structure naturally? The invention is not distinctly claimed.

***Double Patenting***

21. Claims 24-25 of this application conflict with claims 1-7, 20-24 and 32-38 of Application No. 09/462,713. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but

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one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention is directed to a genus claim of producing antibodies and the claims of 09/462,713 is directed to a species of invention; a genus is obvious over a species.

### *Conclusion*

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

24. Fitzgerald et al (US Pat. 6,423,513 and 6,426,075) are cited to show immunogenic PE chimeras.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 23, 2002

*678*  
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